Citation:

Lee GM, Salomon JA, Friedman JF, Hibberd PL, Ross-Degnan D, Zasloff E, Bediako S, Goldmann DA. Illness transmission in the home: a possible role for alcohol-based hand gels. *Pediatrics.* 2005 Apr;115(4):852-60.

PubMed ID: 15805355

Study Design:

Observational, Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The purpose was to assess occurrence of respiratory and gastrointestinal illnesses in families with children enrolled in child care and to study predictors of lower rates of illness transmission in the home.

Inclusion Criteria:

- A family with at least 1 child between 6 months and 5 years old
- A family with at least 1 child in day care with 5 or more other children for 10 or more hours/week
- Family was not planning to move for the duration of the study
- Family had access to a telephone
- Family had a primary care giver that spoke English or Spanish

Exclusion Criteria:

- Any family whose home also functioned as a child care facility for 5 or more children
- Families in which a member whose occupation required working with children aged 6 months to 5 years for 10 or more hours per week.

Description of Study Protocol:

Recruitment - A random number generator identified 250 families from each of 5 pediatric medical practices (3 urban practices and 2 suburban practices) for a total of 1250 families. Recruitment letters were mailed, and subjects were screened for eligibility.

Design - Observational, Prospective Cohort Study

Blinding Used (if applicable): not applicable

Intervention (if applicable): not applicable

Statistical Analysis

- Families with ≥ 4 weeks of records were included in the analysis.

- Secondary illness was calculated by the number of primary illness found in each family, the susceptibility of each family member after exposure, and the secondary illnesses that occurred during the susceptibility. Secondary illness was defined as the amount of secondary illnesses divided by total number of susceptible person-months in a family. 95% confidence intervals were measured for incidence rates using Poisson distribution.
- The 7 seven families who used PDAs for data collection were excluded from additional analysis since the collection methods were different for this group.
- Poisson regression was used at the family level to study possible factors related to reduced transmission of illness.
- Bivariate analysis was used to study the association between clinical variables and secondary transmission.
- Enrollment site was used for fixed effect to consider family differences.
- Use of hand products and hygiene practices were studied as ordinal variables using bivariate analysis.
- Predictors were significant at $p < 0.05$.
- Multivariate analyses were used with forward and backward stepwise Poisson regression with α set at ≤ 0.15 to enter and remove terms to find significant predictors of secondary illness. Variables were frequent users and infrequent users for the multivariate analysis. Enrollment site was again a fixed effect to account for differences.

Data Collection Summary:

Timing of Measurements

- A survey about family beliefs and practices was mailed at the beginning of the study.
- Symptom diaries used to record timing and duration of respiratory and GI illnesses.
- Biweekly telephone calls were placed to review illnesses recorded by participants.
- Families with ≥ 4 weeks of records were included in the analysis.

Dependent Variables

- Respiratory illnesses based on self-report
- Gastrointestinal illnesses based on self-report
- Rates of secondary illness transmission

Independent Variables

- Hand hygiene practices and use of hand hygiene products based on parental report

Control Variables

Description of Actual Data Sample:

Initial N: 1250 families randomly selected. 49% did not meet eligibility criteria. 22% were eligible and contacted for study participation, and 29% were not contacted because study enrollment was complete for each pediatric practice. Of the 278 eligible families who were contacted, 17 families refused to participate and 261 (94%) families were enrolled in the study.

Attrition (final N): 215 families (82%) completed at least 4 weeks of illness transmission data.

Age: 287 children ≤ 5 years of age including those enrolled in child care, 152 children 6–17 years of age, 395 adults ≥ 18 years of age, and 3 whose ages were unknown

Ethnicity: N = 182

- 81 white non-Hispanic (45%)
- 44 black/African-American, non-Hispanic (24%)
- 37 Hispanic/Latino (20%)
- 20 of other ethnicity (11%)

Other relevant demographics:
Educational level of respondents (N = 175)
31 ≤ High school graduate (18%)
86 ≤ College graduate (49%)

58 > College graduate (33%)

Household income (N = 174) 30 respondents < $20,000 (17%)
24 respondents $20,000-$39,999 (14%)
26 respondents $30,000-$59,999 (15%)
25 respondents $60,000-$79,999 (14%)
69 respondents ≥ $80,000 (40%)

Insurance (N = 179)
131 with individual or employee-sponsored coverage (73%)
43 with Medicaid (24%)
5 with other insurance or uninsured (3%)

Anthropometrics

Location: Pediatric medical practices in Boston, Massachusetts

Summary of Results:

Key Findings

- Only two-thirds of respondents believed that contact transmission was important in the spread of colds
- Fewer than half believed that it was important in the spread of stomach flus
- 22% of respondents reported use of alcohol-based hand gels all, most or some of the time
- 33% reported always washing their hands after blowing or wiping a nose
    - Bivariate analysis found that reported use of alcohol-based hand gels reduced transmission of respiratory illness. The multivariate model found that frequent use of alcohol-based hand gels reduced transmission of secondary respiratory illness.
    - Use of hand gels lowered secondary transmission of gastrointestinal illness but was not significant.

Other Findings

- Hand hygiene practices included using water alone, soap, antibacterial soap, and alcohol-based hand gels. A positive correlation was found with use of antibacterial soap and alcohol-based hand gels ($r = 0.417$, $p < .001$). A negative correlation was found with the use of plain soaps and antibacterial soaps ($r = -0.198$, $p = .009$).
- 72% of respondents reported hand washing after every diaper change and 84% washed hands after each trip to the bathroom. Parents who were more likely to report frequent use of hand sanitizing gels were more likely to wash hands after blowing or wiping a nose ($r = 0.215$, $p = .004$).

Respiratory Illness

- 1099 (71%) of 1545 respiratory illnesses were considered to be primary.
- Secondary transmission rates were 0.63 illnesses per susceptible person-month (95% CI: 0.58 - 0.69).
- 239 children of ≤ 5 years of age brought home 592 primary illnesses (54%). 76 children aged 6 to 17 years were responsible for 135 primary illnesses (12%). 234 adults introduced 371 primary illnesses (34%) into the home.

Gastrointestinal Illness

- 297 (83%) of 360 of these gastrointestinal illnesses were primary infections.
- Secondary transmission rates were 0.35 illnesses per susceptible person-month (95% CI: 0.27 - 0.45).
- 123 children of ≤ 5 years of age brought home 171 primary illnesses (58%). 39 children aged 6 to 17 years were responsible for 37 primary illnesses (16%). 63 adults introduced 79 primary illnesses (27%) into the home.
- Bivariate analysis found that a higher educational level and having Medicaid were significantly associated with higher transmission of secondary gastrointestinal illness. Multivariate analysis showed that Medicaid insurance was a significant predictor of increased transmission of secondary illness in the home.

Author Conclusion:

In homes with young children enrolled in child care, use of alcohol-based hand sanitizer reduced the transmission of respiratory illness among family members.

Reviewer Comments:

Population may be more representative of illness transmission rates in the community. Authors note the following limitations:

- *Outcome measures based on reported symptoms or illnesses by the family caregiver, unable to validate the cause of the illnesses by microbiologic diagnoses or serologic assays*
- *Relied upon parental report of frequency of hand hygiene practices, unable to validate independently the quantity of hand hygiene product used or the frequency of hand hygiene practices after common household events such as using the bathroom*
- *Product itself may not necessarily be responsible for the observed protective effect, as the use of the alcohol-based hand gels may simply serve as a proxy for good hand hygiene behaviors*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	N/A

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes

2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	N/A
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	N/A
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A

5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	???
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	???
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	???
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	???
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes

8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes